

## CLAIMS

What is claimed is:

1. A mobile filtration facility comprising:
  - a mobile first housing bounding at least a substantially sterile clean room, a filtration area separated from the clean room, and at least one change room communicating with the clean room; and
  - a fluid filtration system disposed within the first housing, the filtration system comprising:
    - a first support container disposed outside of the clean room, the first support container bounding a compartment;
    - a disposable, open top fill bag disposed within the compartment of the first support container;
    - at least one filter;
    - a disposable first fluid line extending between the fill bag and the at least one filter;
    - a second support container disposed outside of the clean room, the second support container bounding a compartment;
    - a disposable pooling bag disposed within the compartment of the second support container, the pooling bag being in fluid communication with the at least one filter; and
    - a disposable fill line having a first end in fluid communication with the pooling bag and an opposing second end disposed within the clean room.
2. The mobile filtration facility as recited in claim 1, wherein the first housing comprises a standard shipping container having a parallel piped configuration.
3. The mobile filtration facility as recited in claim 2, wherein the shipping container has a width of approximately 2.44 meters, a length of approximately 9.14 meters or 12.20 meters, and height in a range between about 2.59 meters and about 2.90 meters, all dimensions being within a tolerance of 15 cm.
4. The mobile filtration facility as recited in claim 1, further comprising a laminar air flow hood disposed within the clean room, the second end of the fill line being disposed within the laminar air flow hood.

5. The mobile filtration facility as recited in claim 4, further comprising means for dispensing a predetermined quantity of fluid through the fill line.

6. The mobile filtration facility as recited in claim 5, wherein the means for dispensing comprises:

- 5                   a peristaltic pump coupled with the fill line;  
                    a scale disposed within the laminar air flow hood; and  
                    a central processing unit in electrical communication with the peristaltic pump and the scale.

7. The mobile filtration facility as recited in claim 1, further comprising  
10 an air filtration system adapted to filter air within the clean room.

8. The mobile filtration facility as recited in claim 7, wherein the air filtration system produces a positive air pressure within the clean room relative to the filtration area and the at least one change room.

9. The mobile filtration facility as recited in claim 1, wherein the clean  
15 room satisfies ISO Class 5 requirements.

10. The mobile filtration facility as recited in claim 1, wherein the at least one change room comprise a first change room in communication with the filtration area and a second change room extending between the first change room and the clean room, a door being disposed between the first change room and the second change  
20 room.

11. The mobile filtration facility as recited in claim 1, wherein the at least one filter comprises:

- at least one prefilter having a filter membrane with a porosity in a range from about 0.2 $\mu$ m to about 10 $\mu$ m; and  
25                   at least one final filter having a filter membrane with a porosity of about 0.1 $\mu$ m, the at least one prefilter being fluid coupled in series with the at least one final filter.

12. The mobile filtration facility as recited in claim 1, wherein the at least one filter, the pooling bag, and the fill line are preassembled and sterilized as a unit.

30           13. The mobile filtration facility as recited in claim 1, wherein the compartment of the pooling bag has a volume of at least 500 liters.

14. The mobile filtration facility as recited in claim 1, further comprising:  
                    a peristaltic pump; and

a circulation line coupled with the peristaltic pump, the circulation line having a first end fluid coupled with a first port on the pooling bag and a second end fluid coupled with a second port on the pooling bag.

15        15.     The mobile filtration facility as recited in claim 14, further comprising a dip tube at least partially disposed within the pooling bag, the dip tube being in fluid communication with the circulation line.

16.     The mobile filtration facility as recited in claim 1, further comprising a pump coupled with the first fluid line.

10        17.     The mobile filtration facility as recited in claim 1, further comprising:  
the first housing further comprising a packing room;  
a partition wall being formed between the clean room and the packing room; and

a double door pass-through conduit formed on the partition wall so as to enable the transfer of items between the clean room and the packing room.

15        18.     The mobile filtration facility as recited in claim 1, further comprising a mobile second housing discrete from the first housing, the second housing bounding a thaw room and a freezer room.

19.     The mobile filtration facility as recited in claim 18, wherein the second housing comprises a standard cargo container having a parallel piped configuration.

20        20.     The mobile filtration facility as recited in claim 18, wherein the thaw room is bounded by a first wall and an opposing second wall, a plurality of inlet vents substantially covering the first wall and a plurality of return vents substantially covering the second wall so that a substantially uniform air flow can be transferred between the first wall and the second wall.

25        21.     A method for filtering a liquid derived from mammalian blood, the method comprising:

transporting a mobile filtration facility to a first storage facility housing a liquid derived from mammalian blood, the mobile filtration facility comprising a mobile first housing bounding at least a substantially sterile clean room and a filtration area separated from the clean room;

30

delivering a first batch of the liquid into a disposable fill bag located within the filtration area of the first housing;

processing the liquid located within the fill bag through at least one

filter and into a disposable pooling bag so as to obtain a true pool of the first batch of the liquid within the pooling bag; and

dispensing the filtered liquid located within the pooling bag into a plurality of packaging containers located within the clean room.

5        22.    The method as recited in claim 21, wherein the first batch of the unfiltered liquid is initially frozen, the method comprising thawing the first batch of the liquid prior to delivering the first batch of the liquid into the disposable fill bag.

23.    The method as recited in claim 22, further comprising thawing the entire first batch of the liquid within a thaw room of the mobile filtration facility.

10       24.    The method as recited in claim 23, wherein the mobile filtration facility comprises a mobile second housing bounding the thaw room.

25.    The method as recited in claim 21, wherein the act of delivering the first batch of the liquid comprises pouring the first batch of the liquid through a screen and into the fill bag.

15       26.    The method as recited in claim 21, further comprising continuously mixing the liquid within the pooling bag while the liquid is being dispensed into the packaging containers.

27.    The method as recited in claim 21, wherein the liquid derived from mammalian blood comprises serum, plasma, or fractions thereof.

20       28.    The method as recited in claim 21, wherein the act of processing the liquid comprises pumping the liquid through at least one prefilter having a filter membrane with a porosity in a range from about 0.2 $\mu$ m to about 10 $\mu$ m and through at least one final filter having a filter membrane with a porosity of about 0.1 $\mu$ m, the at least one prefilter being fluid coupled in series with the at least one final filter.

25       29.    The method as recited in claim 21, wherein the act of dispensing the liquid comprises:

dispensing a first volume of the liquid into a first packaging container;

weighing the packaging container containing the first volume; and

30       dispensing a second volume of the liquid into a second packaging container, the second volume being based on the weight of the packaging container containing the first volume.

30.    The method as recited in claim 21, wherein the first housing bounds a packaging room that is separated from the clean room by a partition wall, a double

door pass-through conduit is formed on the partition wall, the method further comprising transferring the packaging containers containing the liquid from the clean room to the packaging room through the pass-through conduit.

5       31. The method as recited in claim 21, wherein the mobile filtration facility comprises a mobile second housing bounding a freezer room, the packaging containers containing the blood serum being frozen within the freezer room of the mobile second housing.

      32. The method as recited in claim 21, further comprising:  
      replacing the fill bag, at least one filter, and pooling bag with a new fill  
10       bag, at least filter, and pooling bag, respectively; and  
      delivering the second batch of the liquid into the new fill bag.

      33. The method as recited in claim 21, further comprising:  
      transporting the mobile filtration facility to a second storage facility  
      housing liquid derived from mammalian blood; and  
15       using the mobile filtration facility to filter the liquid of the second  
      storage facility.

      34. The method as recited in claim 21, wherein the second storage facility is in a separate country from the first storage facility.

20       35. A method for filtering mammalian blood serum at a plurality of different locations, the method comprising:

      harvesting and freezing a quantity of mammalian blood serum at a  
      plurality of different locations;  
      moving a mobile filtration facility to each of the different locations;  
      and  
25       filtering and packaging the harvested mammalian blood serum at each  
      of the different locations using the mobile filtration facility.

      36. The method as recited in claim 35, wherein the mobile filtration facility comprises a mobile first housing bounding a clean room and a filtration area separated from the clean room.

30       37. The method as recited in claim 35, wherein the act of filtering and packaging the harvested mammalian blood serum comprises:

      thawing a first batch of the frozen blood serum;  
      delivering the thawed first batch of blood serum into a disposable fill

bag located within the filtration area of the first housing;

processing the blood serum located within the fill bag through at least one filter and into a disposable pooling bag so as to obtain a true pool of the first batch of the blood serum within the pooling bag; and

5 dispensing the blood serum located within the pooling bag into a plurality of packaging containers located within the clean room.

38. The method as recited in claim 35, wherein at least two of the plurality of different locations are located in different countries.

39. The method as recited in claim 35, wherein the blood serum is derived  
10 from a bovine fetus, calf, horse, or pig.

40. A disposable pooling bag assembly comprising:

a flexible pooling bag bounding a compartment, the pooling bag having an inlet port and an outlet port communicating with the compartment;

a filter in fluid communication with the inlet port of the pooling bag;

15 and

a circulation line projecting outside of the compartment of the pooling bag and having opposing ends in fluid communication with the compartment of the pooling bag, wherein the flexible pooling bag, the filter and the circulation line are concurrently sterilized as a preassembled, closed system.

20 41. The disposable pooling bag assembly as recited in claim 40, wherein the compartment of the pooling bag has a volume of at least 500 liters.

42. The disposable pooling bag assembly as recited in claim 40, wherein the filter has a filter membrane with a porosity in a range from about 0.1  $\mu\text{m}$  to about 10  $\mu\text{m}$ .

25 43. The disposable pooling bag assembly as recited in claim 40, further comprising a dip tube at least partially disposed within the compartment of the pooling bag, the dip tube being in fluid communication with the circulation line.

44. The disposable pooling bag assembly as recited in claim 40, further comprising a peristaltic pump coupled with the circulation line outside of the  
30 compartment of the pooling bag.

45. The disposable pooling bag assembly as recited in claim 40, further comprising an elongated fluid line in fluid communication with the outlet port on the pooling bag, the fluid line being concurrently sterilized with the pooling bag.

46. A method for pooling a fluid solution, the method comprising:  
delivering a fluid through at least one filter and into a compartment of  
a sterile, flexible pooling bag so that the fluid is pooled within the pooling bag,  
portions of the fluid having a different composition so that the fluid is not  
homogeneous as the fluid first enters the compartment of the pooling bag;  
5 mixing the pooled fluid within the compartment of the pooling bag so  
that the pooled fluid becomes homogeneous; and  
dispensing the homogeneous, pooled fluid from the compartment of  
the pooling bag.
- 10 47. The method as recited in claim 46, wherein the step of delivering the  
fluid through at least one filter comprises delivering the fluid through a filter train  
comprised of a plurality of interconnected filters.
48. The method as recited in claim 46, wherein the step of delivering the  
fluid through at least one filter comprises delivering the fluid through a filter having a  
15 filter membrane with a porosity in a range from about 0.1  $\mu\text{m}$  to about 10  $\mu\text{m}$ .
49. The method as recited in claim 46, further comprising:  
depositing a first volume of the fluid into a fill container, the fill  
container being fluid coupled with the pooling bag through the at least one  
filter, the fill container bounding a compartment having a volume smaller than  
20 the volume of the chamber of the pooling bag and smaller than the volume of  
the fluid pooled within the pooling bag; and  
progressively adding more of the fluid into the fill container as the  
fluid is delivered from the fill container to the pooling bag.
50. The method as recited in claim 49, further comprising adding one or  
25 more additives into the fluid within the fill container after a portion of fluid has  
already been delivered into the pooling bag.
51. The method as recited in claim 46, wherein the method of mixing the  
pooled fluid comprises using a peristaltic pump to pump the fluid through a  
circulation line projecting from the pooling bag, the circulation line having opposing  
30 ends in fluid communication with the compartment of the pooling bag.